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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,393	02/10/2004	Alan Leslie Cripps	CRIP3001C3/REF	1830

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,393	CRIPPS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *40-51 and 53-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-51 and 53-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/21/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40-51 and 53-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al in view of Weers et al (6,309,623).

Davis et al teach aerosol solutions for drug delivery, where the system contains water, ethanol and propylene glycol. An important finding for Davis et al was that with steroidal compounds the solubility of the drug in the vehicle was of great importance. The presence of ethanol should give the vehicle solvent characteristics without changing physical characteristics (see introduction on page 85). Davis uses flunisolide as an example of a steroidal compound and shows that addition of ethanol improve delivery, and concludes that propylene glycol-ethanol and water systems show that output increases as the ratio of ethanol to propylene glycol increases (see page 91-92). Table 1 on page 87 discloses data for water-propylene glycol systems, which includes various concentrations for ingredients such as ethanol and propylene glycol. The said concentration ranges include 5% to 70% for both ingredients. The 5% propylene glycol is considered to be very close to claimed 3% range.

Davis et al, while disclosing steroidal compounds as a genus, lack disclosure on fluticasone as a species.

Weers et al disclose stabilized formulations for use in metered dose inhalers for aerosol delivery to the respiratory systems. The formulations are generally in a dispersion in a medium comprising hydrofluoroalkane propellants (see abstract and col. 3, lines53-67). Weers et al also disclose a variety of active agents that can be used in the said formulations and list flunisolide and **fluticasone propionate** as suitable candidates for the said formulations (col. 19, lines 55-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one steroidal compound, fluticasone, as disclosed by Weers et al, with another steroidal compound, flunisolide as disclosed by Davis et al, and have produced effective and stable formulations for delivery. In other words, one of ordinary skill in the art would have been motivated to practice the teachings of Davis using other active agents, since Davis is clearly disclosing advantages of the solutions for aerosol delivery.

Claims 40-51 and 53-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbeck et al (5,914,122) in view of Weers et al (6,309623).

Otterbeck et al disclose a stable budesonide solution where budesonide is dissolved in a solvent which may be water, an alcohol such as ethanol, isopropanol or propylene glycol or mixtures thereof (see abstract and col. 2, lines 7-21). It is also disclosed that the solvents could be ethanol, isopropanol, glycerol, polyethylene glycol, propylene glycol, etc (col. 3, line 66 to col. 4, line 4). Otterbeck discloses that the solvent system (water/ethanol/propylene glycol) comprises from 0.001 to 0.1% by weight of the active agent (claim 22). Otterbeck lacks disclosure on fluticasone propionate as the active agent.

Weers et al, discussed above, discloses **fluticasone propionate**, flunisolide and budesonide as suitable active agents for aerosol delivery of the said formulations.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one steroidal compound, fluticasone, as disclosed by Weers et al, with another steroidal compound, budesonide as disclosed by Otterbeck et al, and have produced effective and stable formulations for delivery to respiratory system. In other words, one of ordinary skill in the art would have been motivated to prepare solution formulations as disclosed by Otterbeck et al using other active agents, since Otterbeck et al clearly disclose advantages of the solutions for aerosol delivery.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-51 and 53-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending

Application No. 10/630,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Specifically, the only difference between instant claim 40 and reference claim 1 is that claim 1 is drawn to a metered dose inhaler containing a canister comprising the formulation of fluticasone propionate, propellant and ethanol. Claim 1 also recites an exit orifice diameter. The limitations of the metered dose inhaler are considered conventional and thus instant claims are considered anticipated by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-51 and 53-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/168,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Specifically, the only difference between instant claim 40 and reference claim 1 is that claim 1 is drawn to a formulation comprising salmeterol base, and fluticasone propionate as the active agents, whereas the instant claims are drawn to canister comprising fluticasone propionate. However both claims use the open ended language of comprising. Thus instant claims are considered anticipated by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
March 16, 2006

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER